January 9, 2018

ULab Systems, Inc.
Charlie Wen
President & Chief Technology Officer
101 Jefferson Drive, Suite 212A
Menlo Park, California 94025

Re: K171295
Trade/Device Name: Ulab Systems UDesign
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: November 27, 2017
Received: November 29, 2017

Dear Charlie Wen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K171295

Device Name
ULab Systems UDesign

Indications for Use *(Describe)*
The ULab Systems UDesign is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of ULab Systems UDesign requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

I. Submitter Information

Submitter name: ULab Systems, Inc.
101 Jefferson Drive
Suite 212A
Menlo Park, CA 95025

Contact person: Charlie Wen
President & CTO of ULab Systems, Inc,
Email: charlie@ulabsystems.com
Phone : (650) 868-4935

Date Prepared: 27 November 2017

II. Product Classification

| | |
|---|---|
| Device Name: | ULab Systems UDesign |
| Common Name: | Orthodontic Software |
| CFR Classification: | 21 CRF 872.5470 |
| Device Class: | II |
| Product Code: | PNN, LLZ |

III. Predicate Device

Predicate: 3Shape Ortho System (K152086), 3Shape A/S

IV. Device Description

The ULab Systems UDesign is orthodontic diagnosis and treatment simulation software for use by dental professionals. UDesign imports patient 3-D digital scans and allows the user to diagnose the orthodontic treatment needs of the patient and rapidly develop a treatment plan. The output of the treatment plan may be downloaded as files in standard stereolithographic (STL) format for fabrication of dental casts, which may be used to fabricate sequential aligner trays or retainers.

V. Indications for Use

The ULab Systems UDesign is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the ULab Systems UDesign requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.

VI. Comparison of Intended Use, Indications for Use and Technological Characteristics with the Predicate Device

The subject and the predicate devices share the same intended use as software used by dental professionals in orthodontic treatment planning for management of patients and orthodontic models; inspection, measurement and analysis of the models; treatment simulation; preparation and export of a series of virtual dental casts.

The subject and predicate device are based on the following same technological elements:

- Both are stand-alone software designed for use in management of 3D orthodontic models from patient scans;
- Both may be used to design a series of dental casts;
- Both apply digital imaging tools based on 3D orthodontic models for in orthodontic case archiving, diagnosis, treatment planning and CAD design;
- Both provide virtual planning of orthodontic treatments simulating tooth movements;
- Both support stereolithography (STL file format).

Whereas the predicate device designs custom metal bands, indirect bonding transfer trays and dental casts, the subject device designs only dental casts. The predicate device additionally accepts inputs in multiple formats; the subject device only accepts STL file formats.

VII. Performance Data

Software and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005).

The testing includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

All test results met acceptance criteria, demonstrating the ULab Systems UDesign performs as intended, raises no new or different questions of risk and is substantially equivalent to the predicate device.

VIII. Conclusions

The ULab Systems UDesign has the same intended use as the predicate device. In addition, it has similar technological characteristics; performance data demonstrates that any differences in technological characteristics do not raise different questions of safety or effectiveness. Therefore, the ULab Systems UDesign is substantially equivalent to the cleared predicate device.